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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JONATHAN RETTA, KIRSTEN SCHOFIELD, and JESSICA MANIRE on Behalf of Themselves and all Others Similarly Situated,

Plaintiffs,

v.

MILLENNIUM PRODUCTS, INC.

Defendant.

Case No. 2:15-cv-01801-PSG-AJW

PLAINTIFFS' REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF OPPOSITION TO DEFENDANT'S MOTION TO DISMISS AND MOTION TO STRIKE

Judge: Hon. Philip S. Gutierrez
Hearing Date: August 31, 2015

FAC Filed: May 19, 2015
Trial Date: Not Set

Plaintiffs Jonathan Retta, Kirsten Schofield, and Jessica Manire ("Plaintiffs") respectfully request that the Court take judicial notice of the documents described below and attached hereto pursuant to Federal Rule of Evidence 201 and the incorporation by reference doctrine. This request is made in support of Plaintiffs' Opposition to Defendant's Motion to Dismiss Amended Class Action Complaint and Motion to Strike.

On a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on a Rule 12(b)(6) motion to dismiss, in particular, documents incorporated in the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308, 322 (2007).

A document is incorporated by reference if its "contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [complaint]." *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994). "The court may treat such a document as 'part of the complaint'" and "may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006).

In accordance with this doctrine, Plaintiffs request that the Court take judicial notice of the following document, true and correct copy of which is attached hereto as **Exhibit 1**:

January 31, 2012 Food and Drug Administration Warning Letter to CAW Industries, Inc.

The Warning Letter is incorporated by reference at Paragraph 27 of Plaintiffs' Amended Class Action Complaint. Judicial notice of the Warning Letter is further appropriate under Federal Rule of Evidence 201. The Warning Letter is a document created by a federal agency and published on the federal agency's website, and further reflects the views and policies of the federal government. *See In re Frito-Lay*

N. Am., Inc. All Natural Litig., No. 12-MD-2413 (RRM)(RLM), 2013 WL 4647512, at *4 (E.D.N.Y. Aug. 29, 2013) (holding that "agency letters, policy and guidance documents, websites, and other agency data made available to the public" are subject to judicial notice).

Plaintiffs further request that the Court take judicial notice of the following document, true and correct copy of which is attached hereto as **Exhibit 2**:

> *In re 5-hour ENERGY Mktg. & Sales Practices Litig*., 6/20/2014 Order, MDL 13-2438 PSG (PLAx) (C.D. Cal.) (ECF Doc. No. 43)

Under Rule 201, this Court may take judicial notice of documents filed in any federal or state court, including its own orders. *See United States v. Werneke*, 199 F.3d 906, 909 n. 1 (7th Cir. 1999).

Dated: July 24, 2015

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ L. Timothy Fisher*
L. Timothy Fisher

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EXHIBIT 1

Inspections, Compliance, Enforcement, and Criminal Investigations

CAW Industries, Inc. 1/31/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region 250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

January 31, 2012

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 12 – 2

John W. Willard, Jr.
President
CAW Industries, Inc.
1628 Concourse Court
Rapid City, South Dakota 57703-4761

Dear Mr. Willard:

The Food and Drug Administration (FDA) has reviewed the labeling for your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and your ULTIMATE Concentrate products, including the product labels and your websites at www.dr-willardswater.com and www.drwillard.com. Based on our review, we have concluded that your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate products are misbranded within the meaning of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 343. You may find the Act and the Code of Federal Regulations (CFR) for food labeling through links on FDA's home page at *www.fda.gov.*

Your significant violations are as follows:

Your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate are misbranded within the meaning of section 403(r)(1)(A) of the Act, 21 U.S.C. § 343(r)(1)(A), because the labeling for these products bears nutrient content claims that do not comply with the regulations governing the use of these claims. Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term not defined by regulation in food labeling to characterize the level of a

nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Specifically, your website www.drwillard.com bears the nutrient content claim "very powerful antioxidant." Nutrient content claims using the term "antioxidant" must comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Reference Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim, 21 CFR 101.54(g)(1), and these nutrients must have recognized antioxidant activity, 21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e), 21 CFR 101.54(g)(3). Furthermore, such a claim must include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity, 21 CFR 101.54(g)(4). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

The claim "very powerful antioxidant" as used in your labeling is an unauthorized nutrient content claim. The term "very powerful" characterizes the level of antioxidant nutrients in your product, and therefore, this claim is a nutrient content claim. See section 403(r)(1) of the Act and 21 CFR 101.13(b). Even if we determined that the term "very powerful" could be considered a synonym for a term defined by regulation (e.g., "high" or "high potency"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "very powerful antioxidant" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

Your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate products are further misbranded within the meaning of section 403(r)(1)(A) of the Act because the labeling for these products bears a nutrient content claim that is not authorized by regulation or fails to meet the terms of authorizing regulations.

Specifically, your website www.drwillard.com bears an implied nutrient content claim as defined by 21 CFI 101.13(b)(2)(ii) because it contains statements suggesting that Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and your ULTIMATE Concentrate, because of their nutrient content, may be useful in maintaining healthy dietary practices, and those statements are made in association with claims or statements about nutrients. In particular, your website states that Dr. Willard's Water® CLEAR Concentrate and DARK XXX® Concentrate "ha[ve] 19 trace minerals such as iron, manganese, copper, iodine, zinc, calcium, potassium, and selenium and many others that are essential to maintaining optimun health." Your website also states that Dr. Willard's Water® ULTIMATE Concentrate "has the same concentration of the 19 trace minerals found in the Willard Water® DARK XXX. These trace minerals such as iron, manganese, copper, iodine, zinc, calcium, potassium, and selenium and many others found in the Willard Water® ULTIMATE are essential to maintaining optimum health."

However, these products do not meet the requirements for use of the term "health" as set forth in 21 CFR 101.65(d)(2). To bear an implied nutrient content claim using the term "health," a food, such as your Dr. Willard's Water® products, must: (1.) be low in fat as defined in 21 CFR 101.62(b)(2) (total fat content o 3 g or less per reference amount customarily consumed (RACC) and per 50 g of food); (2.) below in saturated fat as defined in 21 CFR 101.62(c)(2) (saturated fat content of 1 g or less per RACC and not more than 15 percent of calories from saturated fat); (3.) not exceed the disclosure level for cholesterol set forth in 21 CFR 101.13(h)(60 mg cholesterol per 50 g of food); (4.) contain no more than 480 mg sodium per 50 g of food, 21 CFR 101.65(d)(2)(ii)(B); and (5.) must contain at least 10% of the daily value per RACC of one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, and fiber, 21 CFR 101.65(d)(2)(i). But, your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate products do not contain at least 10% of the daily value per RAC(of any of the above nutrients.

Your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate products are misbranded within the meaning of section 403(i)(2) of the Act, 21 U.S.C. § 343(i)(2), because they are fabricated from two or more ingredients but they fail to bear a label that lists the common or usual name of each ingredient. Specifically, your concentrate products are manufactured with

the CAW Micelle catalyst mixture, which is a multi-component ingredient; however the label of these products fails to declare the sub-ingredients (i.e., Calcium Chloride Dihydrate, Castor Oil, Anhydrous Sodium Metasilicate, Magnesium Sulfate, Heptahydrate, U.S.P.) on the label. According to 21 CFR 101.4(b)(2), the requirement to list these component ingredients (or "sub-ingredients") may be met by either parenthetically listing the component ingredients after the common or usual name of the main ingredient, or by listing the component ingredients without listing the ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

Your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate products are misbranded within the meaning of section 403(q) of the Act, 21 U.S.C. § 343(q), because th Nutrition Facts information is not in accordance with 21 CFR 101.9. For example:

- The label statement regarding a serving must be the serving size expressed in common household measure and must be followed by the equivalent metric quantity in parenthesis (fluids in milliliters), 21 CFR 101.9(b)(7). In accordance with 21 CFR 101. 12(c)(1), the reference amount for an unprepared product must be the amount of the unprepared product required to make the reference amount for the prepared product. Therefore, your serving size statement on your product labels must be the amount of the unprepared product required to make the reference amount for the prepared product, i.e., the amount of the concentrate required to make 240 mL. It appears you have expressed the serving size "as prepared" rather than the required "as packaged;"

- Your heading "As Served" in the Nutrition Facts box is not declared in accordance with 21 CFR 101.9(d)(4). The"% Daily Value" (as packaged) is the proper heading for the first column, 21 CFR 101.9(e) and (h)(4);

- A percent DV can not be provided for sugars in accordance with 21 CFR 101.9(d)(7)(ii);

- The column heading "% Daily Value" is not followed by an asterisk as required by 21 CFR 101.9(d)(6);

- Your products declare Sodium as 109, which, in accordance with 21 CFR 101.9(c)(4), must be expressed in milligrams. Further, we note that 10 g of sodium is not consistent with a Daily Value of 0%;

- Your nutrition information is set off in a box as required under 21 CFR 101.9(d)(1)(i). However, the statement of ingredients must not be part of the Nutrition Facts box as your label illustrates.

Your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate are misbranded within the meaning of section 403(a)(1) of the Act, 21 U.S.C. § 343(a)(1), because of the following statement on your website www.dnuillard.com: "Today Dr. Willard's® products are still manufactured by Dr. Willard's family business, CAW Industries, Inc., using state of the art mixing, filling, processing and FDA-approved facilities." This statement is false and misleading because FDA does not approve food manufacturing facilities.

This letter is not meant to be an all-inclusive list of the violations for your products. It is your responsibility to ensure that your products comply with the Act and all applicable implementing regulations. You should take prompt action to correct the violations described in this letter. Failure to do so may result in regulatory action without further notice. Such action may include seizure and/or injunction.

In addition we have the following comments:

- The "Not a significant source of' statement lists the nutrients "cholesterol" and "dietary fiber" which are also declared on the nutrition label, 21 CFR 101.9(f).

- The net quantity of contents statement (i.e., 16 oz -0.473 liters) for your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and your ULTIMATE Concentrate products is not on the principal display panel but to the left of the principal display panel, 21 CFR 101.105(a).

- We have concerns about the following statement made on your website www.dnuillard.com: "Click here for the results of an analysis conducted by the Food and Drug Administration that lists all of th minerals found in Willard Water® products." This statement implies that FDA has validated the mineral composition of your Dr. Willard's Water® CLEAR Concentrate, DARK XXX® Concentrate, and ULTIMATE Concentrate products.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation such as revised labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.
Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the letterhead.

Sincerely,
/S/
Elizabeth A. Waltrip
Acting Director
Minneapolis District

cc: John Willard III
Vice President
CAW Industries, Inc.
1628 Concourse Ct.
Rapid City, SD 57703-4761

CAW Industries, Inc.
P.O. Box 4040
Rapid City, SD 57709

Close Out Letter

- Caw Industries, Inc - Close Out Letter 4/12/13[1]

Page Last Updated: 04/22/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Links on this page:

1. /ICECI/EnforcementActions/WarningLetters/2013/ucm348720.htm

EXHIBIT 2

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

#33/34

CIVIL MINUTES - GENERAL

Case No.	MDL 13-2438 PSG (PLAx)	Date	June 20, 2014
Title	In re 5-hour ENERGY Marketing and Sales Practices Litigation		

Present:	The Honorable Philip S. Gutierrez, United States District Judge	
Wendy K. Hernandez	Not Present	n/a
Deputy Clerk	Court Reporter	Tape No.

Attorneys Present for Plaintiff(s):	Attorneys Present for Defendant(s):
Not Present	Not Present

Proceedings: (In Chambers) Order Re: Defendants' Motion to Dismiss the CAC

Before Defendants filed their motion to dismiss the Consolidated Amended Class Action Complaint ("CAC"), the parties stipulated to a page limit of 35 pages for Defendants' moving brief and Plaintiffs' opposition brief. Dkt. # 31. The Court approved that stipulation. Dkt. # 32.

However, when it came time to file their motion to dismiss, Defendants attempted to circumvent the agreed-upon and ordered page limit by attaching 22 pages of appendices to their brief. Dkt. # 33. Defendants spent four pages in their brief discussing their challenges to four causes of action dependent on the laws of more than a dozen states. They did so by citing a handful of cases applicable to a few states and then referring the Court to their appendices for further information. *See Mem.* 30:21-34:21. Defendants' actions put Plaintiffs, who complied with the page limit, at a clear disadvantage. Defendants' approach also essentially asked the Court to assemble Defendants' arguments for them. The Court will not do so.

The Court, on its own motion, STRIKES the following sections of the parties' briefs:

- Defendants' opening brief: sections V.A and V.B, and appendices B through D
- Plaintiffs' opposition brief: section VI
- Defendants' reply brief: sections VIII.A through VIII.C

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

#33/34

CIVIL MINUTES - GENERAL

Case No.	MDL 13-2438 PSG (PLAx)	Date	June 20, 2014
Title	In re 5-hour ENERGY Marketing and Sales Practices Litigation		

The parties are directed to submit supplemental briefs concerning Plaintiffs' causes of action for violation of the Magnuson-Moss Warranty Act, breach of express warranty, breach of implied warranty, and common law fraud, according to the following schedule:

- Defendants' opening brief (not to exceed 20 pages): July 7, 2014
- Plaintiffs' opposition brief (not to exceed 20 pages): July 21, 2014
- Defendants' reply brief (not to exceed 10 pages): July 28, 2014

The Court will not consider any appendices, or any pages beyond these page limits. The Court cautions the parties that they should not attempt to evade these page limits by making extensive use of footnotes. Finally, the Court reminds the parties that they are not required to use every page they are allotted.

The hearing on Defendants' motion to dismiss is CONTINUED to **August 25, 2014.**

IT IS SO ORDERED.